

REMARKS

Claims 1-54 are pending in the present application.

Claims 5-10 have been amended.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of February 10, 2006 the following actions were taken:

(1) The specification was objected to since the abstract was not presented on a separate sheet of paper;

(2) Claims 5-10 were rejected under 35 U.S.C. § 112, second paragraph, as having insufficient antecedent basis;

(3) Claims 1-4, 6, 7, and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by an academic article entitled "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yukiyoshi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto");

(4) Claims 1-4 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by an academic article entitled "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb");

(5) Claims 1-8, 19-21, 29-31, 38-40, 44-46, 48-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");

(6) Claims 1-9, 11, 19, 22-24, 28-31, 38-40, 44-46, and 48-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");

(7) Claims 1-4, 15-24, 26-31, 34-40, 43-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427");

(8) Claims 19 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsu in view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper");

(9) Claims 1, 13-14, 32-33, 41-42, and 50-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ashmead '427 in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International

Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter “Izumi”);

(10) Claims 1-13, 19-33, 38-42, 44-46, 48-51, and 53-54 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claim 1-13, 17-30, 33-37, 40-46, and 49-51 of copending Application No. 10/829,468.

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

*Objection of the Abstract*

The Examiner has objected to the abstract as not commencing on a separate sheet in accordance with 37 C.F.R. 1.52(b)(4). The Applicant has provided the abstract on a separate sheet in compliance with 37 C.F.R. 1.52(b)(4), please see the following page. As such, the Applicant respectfully requests that this objection be withdrawn.

Claim objections and Rejections under 35 U.S.C. § 112, second paragraph

Claims 5-10 were rejected under 35 U.S.C. 112, second paragraph, as having insufficient antecedent basis. Claims 5-10 have been amended to correct the antecedent basis issues and a typographical error. Therefore, the Applicant respectfully requests that these rejections be withdrawn.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-12, 15-24, 26-31, 34-40, 43-49, and 52-54 as being anticipated by several references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided.

*Composition Claims 1 and 19*

The Examiner has rejected claim 1 and/or 19 by several general amino acid chelate references; specifically, Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. However, none of the references provide a hypoallergenic metal amino acid chelate composition as required by independent claims 1 and 19. The Ashmead '427 reference cited by the Examiner suggests that the Lumb and Nakamoto references do not even disclose a general amino acid chelate. The Examiner references the Ashmead '427 patent, which states "in order for a true chelate to be formed the mole ratio of protein hydrolysate ligand or amino acid ligand to metal must be at least 2:1 and the reaction conditions must favor the formation of a chelate by the removal of potentially interfering protons." See col. 5, lines 59-63. Actual

experimental conditions in the Lumb and Nakamoto references are sparse at best. Nakamoto merely states “[m]ost of the compounds were prepared by standard procedures,” giving no further guidance. See page 4529, Experimental Section. Additionally, Lumb never states exactly how the chelate forms, instead he explains how he calculates the stability constants for his alleged chelates through potentiometric determination. See page 690. In fact, in the abstract, Lumb discloses that the “probable” structures of the chelates are “suggested.” See page 690. It is unclear if the chelates were supposedly formed from the metal chloride and glutamic and aspartic acid solutions as he performed his pH measurements or from some other source. See page 690, col. 2. Under the Ashmead ‘427 definition, it is doubtful that Lumb or Nakamoto formed chelates. Clearly, neither of these references contain enough disclosure to enable anyone to properly make an amino acid chelated. Regardless of enablement, neither Lumb or Nakamoto disclose a hypoallergenic chelated composition.

Additionally, the Hsu, Ashmead ‘424, and Ashmead ‘427 references fail to teach a hypoallergenic chelate composition. In fact, the references never mention hypoallergenic at all. The Applicant has claimed a specific narrow class of chelates. The chelates must contain hypoallergenic components that are substantially free of allergens. The Examiner has stated that ““once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show the unobvious difference.””

See Office Action, page 4 (citing MPEP 2113). The Applicant contends that the composition is different than those found by the Examiner in Lumb, Nakamoto, Hsu, Ashmead ‘424, and Ashmead ‘427. The Applicant has already discussed that Lumb and Nakamoto are probably not true chelates as defined by Ashmead ‘427. Even so, none of these chelates claim to be hypoallergenic and nothing in the references suggest that these chelates are hypoallergenic. As mentioned, the current independent claims specifically require that the chelates be substantially free of allergens. This requirement significantly changes the composition of the final product. Under this definition, the referenced chelates would fail to qualify as such, since the references do not use hypoallergenic materials or ensure that the final product is hypoallergenic. As the Examiner has not provided a single reference that contains each and every element of the present invention, the Applicant respectfully requests that the Examiner withdraw the current 102 rejections.

*Method Claims 38 and 46*

The Examiner has rejected claim 38 and 46 by several references; specifically, Hsu, Ashmead '424, and Ashmead '427. However, none of these references provide a method of preparing or administering a hypoallergenic metal amino acid chelate composition. The Applicant renews the arguments previously made with respect to these references above. Independent claims 38 and 46 specifically require an affirmative hypoallergenic determination. Each independent method claim requires a determination of the individual metal and amino acid components for chelation. The present specification is specific in defining the terms hypoallergenic, allergy, and allergen, so that no ambiguity arises as to the Applicants' methods and compositions. See page 8, lines 12-29. None of the references provided by the Examiner refers to any such determination as required by claims 38 and 46. Therefore, the Examiner has not provided a reference that requires every element of the method claims.

Since the Examiner has not provided any single reference that provides each and every element of the present claims, the Applicant respectfully requests that current 102 rejections be withdrawn. As the Applicant has explained the novelty of the independent method claims over the prior art, the Applicant respectfully requests that the Examiner withdraw the 102 rejections for the corresponding dependent claims as well.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 13-14, 19, 25, 32-33, 41-42, and 50-51 under 35 U.S.C. 103(a) as being unpatentable over several references.

Applicant does not deem it necessary to recite the entire case law standard required in order to establish a *prima facie* case of obviousness. However, Applicant would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely that the asserted references as modified or combined must: 1) teach or suggest each and every element of the claimed invention; 2) provide sufficient motivation for the modification or combination asserted; and 3) provide a sufficient likelihood of successfully making the modification or combination.

Emphasis on the two independent compositional claims is provided herein, as the Applicants assert that these claims are all patentably distinct over the prior art. Specifically, the Examiner has rejected claims 1, 13-14, 19, 25, 32-33, 41-42, and 50-51 as being obvious in view of various combinations of Hsu, Cooper, Ashmead '427, and Izumi. Specifically, as

the Examiner has rejected two independent claims, 1 and 19, a discussion of these claims is provided.

*Composition Claim 1*

The Examiner has combined two references, specifically Ashmead '427 and Izumi, to reject claims 1, 13-14, 32-33, 41-42, and 50-51. The Examiner has combined these references since Ashmead '427 fails to teach "1) a method other than protein hydrolysis; 2) protein hydrolysis and wherein the protein used in the hydrolysis is hypoallergenic." See Office Action, page 11. The Examiner then states that Izumi teaches multiple methods including "enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods." See Office Action, page 11. However, as previously mentioned, where does Izumi teach the hypoallergenic element required by all four independent claims? All four independent claims require a hypoallergenic character, which is defined very specifically in the specification. The two compositional claims require that the hypoallergenic chelate be substantially free of allergens such that the chelate does not cause a discernable adverse allergic reaction in a subject. The two independent method claims require that specific affirmative hypoallergenic determination steps are made with respect to both the metal and amino acid and that the final product be a hypoallergenic chelate. Izumi never mentions that its amino acid methods are hypoallergenic or that it produces a hypoallergenic product. Additionally, as previously discussed, Ashmead '427 also does not teach a hypoallergenic composition. Therefore, the combination of these two references would not successfully provide a hypoallergenic metal amino acid chelate composition as required by composition claim 1. In fact, the Examiner has not shown any such language in any reference in the current office action. The remaining rejected claims are dependent claims. The Applicant contends that every dependent claim also contains the hypoallergenic requirement through dependency. As such, the Applicant submits that these claims are also novel in view of the prior art.

As the Examiner has not provided a combination of references that teach or suggest every element of the claimed invention and as the current combination of references would have no likelihood of success in producing the Applicant's invention, the Applicant respectfully requests that the corresponding 103 rejections be withdrawn.

*Composition Claim 19*

The Examiner has combined two references, specifically Hsu and Cooper, to reject claims 19 and 25. As previously discussed, Hsu does not teach a hypoallergenic chelate composition. The Examiner has also identified this limitation, stating “Hsu et al. do not expressly disclose a composition wherein the formulation additive is a hypoallergenic flow control agent . . .” See Office Action, page 9. The Examiner then relies on Cooper as teaching the use of “the lubricant stearic acid.” See Office Action, page 10. But where does Cooper teach a hypoallergenic flow control agent as identified by the Examiner? Cooper never states that the stearic acid is hypoallergenic or that any other materials or products are hypoallergenic. The Examiner has not shown any such language in any reference in the current office action, nor has the Examiner has provided a combination of references that teach or suggest every element of the claimed invention. As such, the combination of these two references would not successfully provide a hypoallergenic chelate composition. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

*Double Patenting*

The Examiner has provisionally rejected claims 1-13, 19-33, 38-42, 44-46, 48-51, and 53-54 under the judicially created doctrine of double patenting as being unpatentable over claims 1-13, 17-30, 33-37, 40-46, and 49-51 of Applicant’s copending U.S. Patent Application serial no. 10/829,468. Without conceding the correctness of the rejection and for the sole purpose of advancing prosecution in the present application, Applicant has enclosed herewith a terminal disclaimer disclaiming the terminal portion of any patent issuing from the present application which extends beyond that of any patent to issue from U.S. Patent Application serial no. 10/829,468. Applicant submits that such terminal disclaimer renders the issue of double patenting moot and therefore requests that the rejection be withdrawn.

*Conclusion*

Because the Examiner has not shown any reference that teaches a hypoallergenic chelate composition, the Applicant respectfully asserts the Examiner has not satisfied the requirement for establishing a case of *prima facie* anticipation or of *prima facie* obviousness. Therefore, it is believed the amended claim set should be allowable. Reconsideration is respectfully requested.

In view of the foregoing, Applicants believe that claims 1-54 present allowable subject matter and allowance is respectfully requested. If any impediment to the entry of the present amendment and reconsideration of the claims in view thereof remains which could be removed during a telephone interview, the Examiner is invited to telephone Mr. Gary Oakeson of this office, or in his absence, M. Wayne Western, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 10<sup>th</sup> day of May, 2006.

Respectfully submitted,



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